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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO. VB
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[Handwritten notes in the left margin, including "10/1/95" and "10/1/95"]

EXAMINER
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ART UNIT	PAPER NUMBER 9
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No  
**09/174,937**

Applicant(s)  
**CURTIS et al.**

Examiner  
**Gabriele E. Bugaisky**

Group Art Unit  
**1653**



X Responsive to communication(s) filed on Jan 18, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed**  
in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11, 453 O.G. 213

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

- X Claim(s) 1, 2, 4, 5, 8-12, and 27-39 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
Claim(s) \_\_\_\_\_ is/are allowed.  
X Claim(s) 1, 2, 4, 5, 8-12, and 27-39 is/are rejected.  
Claim(s) \_\_\_\_\_ is/are objected to.  
Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- X See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.  
X The specification is objected to by the Examiner.  
The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.  
☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).  
\*Certified copies not received: \_\_\_\_\_  
Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- Notice of References Cited, PTO-892  
X Information Disclosure Statement(s), PTO-1449, Paper No(s). 4  
Interview Summary, PTO-413  
X Notice of Draftsperson's Patent Drawing Review, PTO-948  
Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

The preliminary amendment of 1/18/2000 is acknowledged. Claims 3, 6-7 and 13-26 have been canceled and new claims 27-39 have been submitted. Claims currently pending are 1-2, 4-5, 8-12 and 27-39.

### ***Election/Restriction***

Applicant's election of Group I in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

It is noted that Applicants have canceled all claims directed to the non-elected inventions.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Information Disclosure Statement***

The listing of references in the specification (e.g., page 25 ) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

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References DG-DN have not been considered as they are results of a sequence search and do not appear to be published references. If Applicants wish the Examiner to consider these results of the submitted searches, it is suggested that they be submitted as part of a declaration.

### ***Drawings***

The drawings are objected to by the draftsman, as summarized on the enclosed PTO-948.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

### ***Specification***

The attempt to incorporate subject matter into this application (e.g. page 10, lines 19-24, page 11, lines 27-29) by reference to published journal articles is improper because only issued U.S. applications may be properly be incorporated by reference.

The disclosure is objected to because of the following informalities: all of the ATCC Accession Numbers (e.g., page 2, line 33, page 3, lines 27, 32 and 38, etc) have been left blank..

Appropriate correction is required.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

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***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title

Claims 1-2, 4-5, 8-12 and 29-39 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial utility or a well established utility. It is stated that, based on sequence analysis and an apparent 66-70% identity of about 400-500 translated nucleotides to *mus* NIP2 and/or human Bcl2/E1B 19kD interacting protein 2, that the instant nucleic acids encode homologs of NIP2 and that they thus play some role in regulation of apoptosis. All function of the encoded proteins is by inference; no information is provided that the instant genes & constructs do indeed regulate apoptosis under any conditions. A starting material that can only be used to produce a final product does not have a substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the proteins that are to be produced as final products resulting from processes involving the claimed cDNA have asserted or identified specific and substantial utilities. The research contemplated by Applicants to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of the protein itself or the mechanisms in which the protein is involved does not define a "real world" context of use. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the cDNA compounds such that another non-asserted utility would be well established for the compounds.

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A sequence search by the examiner of SEQ ID NO:1, for example, showed that nucleotides 2585-3076 share an approximately 80% similarity to human sialoadhesin family 4 (SAF-1) cDNA, that nucleotides 2609-3076 also share an approximately 82% similarity to a nucleic acid encoding human aminopeptidase P (see attached sequence comparisons). Because the results of the examiner's search revealed a high degree of sequence similarity to genes encoding proteins unrelated to NIP2, further doubt is cast upon the utility and function of these disclosed sequences. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention

Claims 1-2, 4-5, 8-12 and 29-39 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear whether the claim is directed to a nucleic acid comprising the instantly disclosed polynucleotide sequences and one encoding a heterologous protein (which may not be contiguous) or whether the claimed nucleic acid encodes a fusion protein comprising the instantly disclosed nucleotide sequences joined to a heterologous sequence.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 38, 9 11 12 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyd *et al.* (ref. A1). The reference provides cDNA encoding Nip2 (Genbank accession # U15173), plasmids containing the construct and recombinantly produced protein. It is deemed anticipatory for the claimed subject matter because nucleotides 908-976 of Nip2 encode amino acids 257-279 of SEQ ID NO:2 (see attached sequence comparison) and thus comprises a

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nucleotide which encodes a fragment of a polypeptide comprising the amino acid sequence of SEQ ID NO:2, wherein the fragment comprises at least 15 contiguous amino acids of SEQ ID NO:2

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Gabriele E. Bugaisky, Ph.D. whose telephone number is (703) 308-4201. The Examiner can normally be reached from 7:30 AM to 1:30 PM (Eastern time zone) on weekdays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher S. F. Low, can be reached at (703) 308-2923.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242.



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Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

  
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April 10, 2000